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Federal Agencies

July 16, 2002

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Commissioner for Patents  
Washington, D.C. 20231

Art Unit 1646

Re: U.S. Utility Patent Application  
Appl. No. 09/943,084; Filed: August 31, 2001  
For: **Prolonged Delivery of Peptides**  
Inventors: KIM *et al.*  
Our Ref: 1658.0020003/MAC/MBT

**AS FILED**  
7/17/02  
**RECEIVED**  
JUL 18 2002  
TECH CENTER 1600/2900

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Form PTO-1449 (citing 82 documents - 10 pp);
3. 82 cited documents (AA1, AB1, AC1, AD1, AE1, AF1, AG1, AH1, AI1, AJ1, AK1, AL1, AM1, AN1, AO1, AP1, AR1, AS1, AT1, AA2, AB2, AC2, AD2, AE2, AF2, AG2, AH2, AI2, AL2, AM2, AN2, AO2, AP2, AR2, AS2, AT2, AL3, AM3, AN3, AO3, AP3, AR3, AS3, AT3, AL4, AM4, AN4, AO4, AP4, AR4, AS4, AT4, AL5, AM5, AN5, AO5, AP5, AR5, AS5, AT5, AL6, AM6, AN6, AO6, AP6, AR6, AS6, AT6, AL7, AM7, AR7, AS7, AT7, AR8, AS8, AT8, AR9, AS9, AT9, AR10, AS10, and AT10); and
4. Return postcard.


It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
July 16, 2002  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Michele A. Cimbala  
Attorney for Applicants  
Registration No. 33,851

Enclosures

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SKGF Rev. 2/15/02 dcw



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re application of:

KIM *et al.*

Appl. No. 09/943,084

Filed: August 31, 2001

For: **Prolonged Delivery of Peptides**

Confirmation No. 7681

Art Unit: 1646

Examiner: S. Huff

Atty. Docket: 1658.0020003/MAC/MBT

**Information Disclosure Statement**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of these documents is provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicant's undersigned representative submits the following concise explanation of the relevance of the non-English language documents, Document Nos. AP1, AL4, AN4, AP4, AO7 and AP7, cited on form PTO 1449:

Document AP1, Patent No. JP 63-91325 is in the Japanese language. An English language family member of Document AP1 is submitted herewith as Document AC1, United States Patent No. 4,853,226. Document AP1 is believed to disclose a sustained release particulate preparation comprising a polymeric compound which is capable of being degraded in the body, wherein the polymeric compound comprises a natural high molecular weight compound of sugar origin. Document AP1 is believed to also disclose a method of making said particulate preparation.

Document AO3, Patent No. JP 4-210928 is in the Japanese language. Document AO3 is believed to disclose a pharmaceutical composition comprising a pharmacologically useful

polypeptide and a polymer and which provide continuous release of the polypeptide over an extended period in an aqueous solution.

Document AP3, Patent No. JP 4-230210 is in the Japanese language. English language family members of Document AP3 are submitted herewith as Document AH1, United States Patent No. 5,091,185, Document AK1, United States Patent No. 5,156,851, Document AB2, United States Patent No. 5,232,708 and Document AL3, European Patent Number EP 0 462 959 B1. Document AP3 is believed to disclose a solid dosage form of bioactive materials to supply growth hormones such as somatotropin for subcutaneous sustained release. The solid dosage form is coated with polyvinyl alcohol.

Document AL4, Patent No. JP 4-283510 is in the Japanese language. English language family members of Document AL4 are submitted herewith as Document AD2, United States Patent No. 5,536,508, Document AI2, United States Patent No. 5,700,486 and and Document AN3, European Publication Number EP 0 486 959 B1. Document AL4 is believed to disclose a pharmaceutical composition for controlled release of a pharmacologically active agent in the form of a particle comprising a biodegradable polymer, an amphiphilic polymer, an agent modifying the interface properties of the particles and a pharmalogically active substance , and methods of making said pharmaceutical composition.

Document AL7, Patent No. DE 195 30 865 A1 is in the German language. An English language family member of Document AL7 is submitted herewith as Document AM7, WIPO Publication No. WO 97/07814. An English language Derwent abstract of Document AP7 is also submitted herewith as Document AT10. Document AL7 is believed to disclose a composition for parenteral administration comprising a source of nutrients and an insulinotropic peptide and a method of non-alimentary nutrition comprising the use of said composition.

Document No. AP6, Patent No. FR 2 732 894, is in the French language. The English language Derwent abstract is submitted herewith as Document AS10. Document AP6 is believed to disclose the use of a  $\beta$ -3 adrenergic agonist to prepare medicaments capable of increasing glucagon-like hormone, GLP-1. Also disclosed is believed to be a method of using a  $\beta$ -3 adrenergic agonist in a method of treatment.

Document AT5, *Krówczyński, Kierownik Katedry Farmacji Stosowanej AM w Krakowie, Warszawa*, pp. 220, 463-464, 490 and 502 (1969), is in the Polish language. Document AT5 is an excerpt from a pharmacology textbook and is believed to disclose that peanut oil and other oils are generally known as pharmaceutical additives.

Accordingly, no English language abstracts or translations are provided for Documents AP1, AO3, AP3, AL4, AL7, AP6, or AT5.

Except for Document AS6, where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. The publication month was not available to the Applicant for Document AS6. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

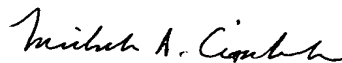
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Date: 7/16/02

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FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1658.0020003/MAC/MBTAPPLICATION NO.  
09/943,084APPLICANT  
KIM et al.FILING DATE  
August 31, 2001GROUP  
1646

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA1	4,526,938	07/02/1985	Churchill et al.	525	415	04/15/1983
	AB1	4,654,324	03/31/1987	Chance et al.	514	12	12/17/1984
	AC1	4,853,226	08/01/1989	Machida et al.	424	426	10/07/1987
	AD1	4,857,505	08/15/1989	Arendt	514	2	03/09/1987
	AE1	4,942,035	07/17/1990	Churchill et al.	424	423	03/27/1985
	AF1	4,985,404	01/15/1991	Mitchell	514	6	06/29/1988
	AG1	B1 4,985,404	04/21/1992	Mitchell	514	6	06/29/1988
	AH1	5,091,185	02/25/1992	Castillo et al.	424	438	06/20/1990
	AI1	5,118,666	06/02/1992	Habener	514	12	06/01/1990
	AJ1	5,120,712	06/09/1992	Habener	514	12	06/01/1990
	AK1	5,156,851	10/20/1992	Castillo et al.	424	497	09/19/1991

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL1	EP 0 092 918 A2	11/02/1983	Europe			Yes No
	AM1	EP 0 177 478 A2	04/09/1986	Europe			Yes No
	AN1	WO 87/06941 A1	11/19/1987	WIPO			Yes No
	AO1	EP 0 263 490 B1	04/13/1988	Europe			Yes No
	AP1	JP 63-91325	04/22/1988	Japan			Yes X No

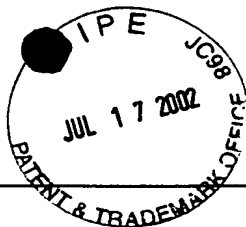
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Ballard, B.E., "Chapter 91: Prolonged-Action Pharmaceuticals," in <i>Remington's Pharmaceutical Sciences</i> , 16 <sup>th</sup> Edition, Osol, A. (ed.), Mack Printing Company, Easton, PA, pp. 1594-1613 (1980).
	AS	1	Bell, G.I. et al., "Hamster preproglucagon contains the sequence of glucagon and two related peptides," <i>Nature</i> 302:716-718, Macmillan Journals Ltd. (1983).
	AT	1	Biessels, G.-J. et al., "Place Learning and Hippocampal Synaptic Plasticity in Streptozotocin-Induced Diabetic Rats," <i>Diabetes</i> 45: 1259-1266, The American Diabetes Association (September 1996).

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA2	5,175,145	12/29/1992	Cooper	514	4	01/14/1992
	AB2	5,232,708	08/03/1993	Castillo et al.	424	497	05/21/1992
	AC2	5,424,286	06/13/1995	Eng	514	2	05/24/1993
	AD2	5,536,508	07/16/1996	Canal et al.	424	501	10/21/1993
	AE2	5,545,618	08/13/1996	Buckley et al.	514	12	12/10/1993
	AF2	5,574,008	11/12/1996	Johnson et al.	514	12	08/30/1994
	AG2	5,614,492	03/25/1997	Habener	514	12	11/23/1993
	AH2	5,631,224	05/20/1997	Efendic et al.	514	12	10/13/1994
	AI2	5,700,486	12/23/1997	Canal et al.	424	501	04/30/1996
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL2	WO 88/07366 A1	10/06/1988	WIPO			Yes No
	AM2	EP 0 343 696 A2	11/29/1989	Europe			Yes No
	AN2	WO 90/11296 A1	10/04/1990	WIPO			Yes No
	AO2	WO 91/11457 A1	08/08/1991	WIPO			Yes No
	AP2	EP 0 442 671 A2	08/21/1991	Europe			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

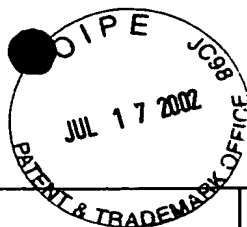
	AR	2	Blackmore, P.F. et al., "Absence of insulinotropic glucagon-like peptide-I(7-37) receptors on isolated rat liver hepatocytes," <i>FEBS</i> 283:7-10, Federation of European Biochemical Societies and Elsevier Science Publishers B.V. (1991).
	AS	2	Cross, S.E. and Roberts, M.S., "Subcutaneous Absorption Kinetics and Local Tissue Distribution of Interferon and Other Solutes," <i>J. Pharm. Pharmacol.</i> 45:606-609, Pharmaceutical Press (July 1993).
	AT	2	Deckert, T. et al., "Absorption of NPH-Insulin from Subcutaneous Tissue: A Methodological Study in Pigs," <i>Acta Pharmacol. Toxicol. (Copenh.)</i> 51:30-37, Munksgaard International Publishers Limited (1982).

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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.





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Page 1 of 1

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1658.0020003/MAC/MBT

APPLICATION NO.  
09/943,084

APPLICANT  
KIM et al.

FILING DATE  
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**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA						
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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL3	EP 0 462 959 B1	12/27/1991	Europe			Yes No
	AM3	EP 0 473 268 A2	03/04/1992	Europe			Yes No
	AN3	EP 0 486 959 B1	05/27/1992	Europe			Yes No
	AO3	JP 4-210928	08/03/1992	Japan			Yes No
	AP3	JP 4-230210	08/19/1992	Japan			Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>3</u>	Gennaro, A.R., "Chapter 23: Inorganic Pharmaceutical Chemistry," in <i>Remington's Pharmaceutical Sciences</i> , 16 <sup>th</sup> Edition, Osol, A. (ed.), Mack Publishing Co., Easton, PA, pp. 343-363 (1980).
	AS	<u>3</u>	Ghiglione, M. et al., "How glucagon-like is glucagon-like peptide-1?" <i>Diabetologia</i> 27:599-600, Springer-Verlag (1984).
	AT	<u>3</u>	Gill, I.J. et al., "Cyclodextrins as protection agents against enhancer damage in nasal delivery systems II. Effect on in vivo absorption of insulin and histopathology of nasal membrane," <i>Eur. J. Pharm. Sci.</i> 1:237-248, Elsevier Science B.V. (June 1994).

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Page 4 of 4

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL4	JP 4-283510	10/08/1992	Japan			Yes X No
	AM4	EP 0 526 862 A1	02/10/1993	Europe			Yes No
	AN4	WO 93/18785 A1	09/30/1993	WIPO			Yes X No
	AO4	WO 93/18786 A1	09/30/1993	WIPO			Yes No
	AP4	WO 93/19175 A1	09/30/1993	WIPO			Yes X No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	4	Heinrich, G. et al., "Pre-Proglucagon Messenger Ribonucleic Acid: Nucleotide and Encoded Amino Acid Sequences of the Rat Pancreatic Complementary Deoxyribonucleic Acid," <i>Endocrinology</i> 115:2176-2181, The Endocrine Society (1984).
	AS	4	Hendrick, G.K. et al., "Glucagon-like Peptide-I-(7-37) Suppresses Hyperglycemia in Rats," <i>Metabolism</i> 42:1-6, W.B. Saunders Company (January 1993).
	AT	4	Hirano, K. and Yamada, H., "Studies on the Absorption of Practically Water-Insoluble Drugs following Injection VIII: Comparison of the Subcutaneous Absorption Rates from Aqueous Suspensions in the Mouse, Rat and Rabbit," <i>J. Pharm. Sci.</i> 72:608-612, American Pharmaceutical Association (1983).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL5	WO 93/25579 A1	12/23/1993	WIPO			Yes No
	AM5	EP 0 619 322 A2	10/12/1994	Europe			Yes No
	AN5	WO 95/05848 A1	03/02/1995	WIPO			Yes No
	AO5	WO 95/07098 A1	03/16/1995	WIPO			Yes No
	AP5	WO 95/17510 A1	06/29/1995	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	5	Holst, J.J. et al., "Truncated glucagon-like peptide-I, an insulin-releasing hormone from the distal gut," <i>FEBS Lett.</i> 211:169-174, Federation of European Biochemical Societies and Elsevier Science Publishers B.V. (Biomedical Division) (1987).
	AS	5	Kreymann, B. et al., "Glucagon-like Peptide-1 7-36: A Physiological Incretin in Man," <i>Lancet</i> 2:1300-1304, The Lancet Publishing Group (1987).
	AT	5	Krówczyński, L., "Technologia postaci leków (technologic galenowa)," Kierownik Katedry Farmacji Stosowanej AM w Krakowie, Warszawa, pp. 220, 463-464, 490 and 502 (1969).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL6	WO 95/31214 A1	11/23/1995	WIPO			Yes No
	AM6	EP 0 658 568 A1	06/21/1995	Europe			Yes No
	AN6	WO 96/20005 A1	07/04/1996	WIPO			Yes No
	AO6	EP 0 733 644 A1	09/25/1996	Europe			Yes No
	AP6	FR 2 732 894	10/18/1996	France			Yes No

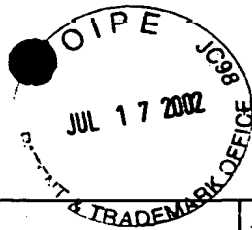
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>6</u>	Lacy, P.E. and Kostianovsky, M., "Method for the Isolation of Intact Islets of Langerhans from the Rat Pancreas," <i>Diabetes</i> 16:35-39, The American Diabetes Association (1967).
AS	<u>6</u>	Lahey, J.R.T. <i>et al.</i> , "Dietary Lipid Content influences the Clinical and Intestinal Adaptive Responses to Islet Transplantation in Diabetic Rats," <i>Diabetes Res.</i> 19:149-164, Teviot-Kimpton Publications (1992).
AT	<u>6</u>	Lehninger, A.L. <i>et al.</i> , "Biochemistry," Worth Publishing, New York, NY, p. 62 (1975).

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	AL7	DE 195 30 865 A1	02/27/1997	Germany			Yes No
	AM7	WO 97/07814	03/06/1997	WIPO			Yes No
	AN7						Yes No
	AO7						Yes X No
	AP7						Yes X No

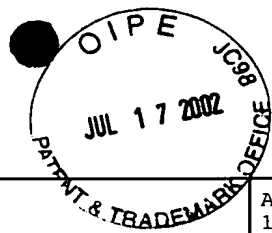
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	7	Lopez, L.C. <i>et al.</i> , "Mammalian pancreatic preproglucagon contains three glucagon-related peptides," <i>Proc. Natl. Acad. Sci. USA</i> 80:5485-5489, The National Academy of Sciences of the U.S.A. (1983).
AS	7	Mosjov, S., "Structural requirements for biological activity of glucagon-like peptide-I," <i>Int. J. Peptide Protein Res.</i> 40:333-343, Munksgaard International Publishers Ltd. (September/October 1992).
AT	7	Nara, E. <i>et al.</i> , "A new method for assessment of drug absorption from muscle: application of a local perfusion system," <i>J. Pharm. Pharmacol.</i> 43:272-274, Pharmaceutical Press (1991).

EXAMINER

DATE CONSIDERED

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.  
1658.0020003/MAC/MBTAPPLICATION NO.  
09/943,084APPLICANT  
KIM *et al.*FILING DATE  
August 31, 2001GROUP  
1646

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
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	AH						
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	AK						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL8						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	8	Seshiah, V. <i>et al.</i> , "Effect of Bed Time Intermediate Acting Insulin in NIDDM Subjects Refractory to a Combination of Sulphonylureas and Biguanides," <i>JAPI</i> 40:666-668, The Association of Physicians of India (October 1992).
	AS	8	Supersaxo, A. <i>et al.</i> , "Effect of Molecular Weight on the Lymphatic Absorption of Water-Soluble Compounds Following Subcutaneous Administration," <i>Pharm. Res.</i> 7:167-169, Plenum Publishing Corporation (1990).
	AT	8	Suzuki, S. <i>et al.</i> , "Comparison of the Effects of Various C-Terminal and N-Terminal Fragment Peptides of Glucagon-Like Peptide-1 on Insulin and Glucagon Release from the Isolated Perfused Rat Pancreas," <i>Endocrinology</i> 125:3109-3114, The Endocrine Society (1989).

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	AO						Yes No
	AP						Yes No

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AR	2	Conn's Current Therapy, Rakel, R.E. (ed.), W.B. Saunders Company, Philadelphia, p. 483 (1989).
AS	2	Dorland's Illustrated Medical Dictionary, Edition 28, W.B. Saunders Company, Philadelphia, p. 1613 (September 1994).
AT	2	Roget's International Thesaurus, Third Edition, Thomas Y. Crowell Company, Inc., New York, pp. 36 and 769 (1962).

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>10</u>	Remington's Pharmaceutical Sciences, 16 <sup>th</sup> Edition, Osol, A. (ed.), Mack Printing Company, Easton, PA, pp. 1448, 1450, 1451, 1453, 1467 and 1555 (1980).
AS	<u>10</u>	Dialog File 351, Derwent World Patent Index Accession No. 10982383, Abstract for FR 2 732 894 A1.
AT	<u>10</u>	Dialog File 351, Derwent World Patent Index Accession No. 11168515, Abstract for DE 19530865 A1.

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